UK Health Security Agency

Publications gateway number: GOV-11416

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) Risk Groups Patient Group Direction (PGD)

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 6 weeks of age with an underlying medical condition which puts them at increased risk from pneumococcal disease.

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	PCV Risk Groups PGD
Version no:	v05.00
Valid from:	1 March 2022
Review date:	1 September 2023
Expiry date:	28 February 2024

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of the publicly funded immunisation in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

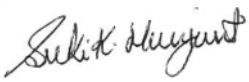
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	03/02/2017
V02.00	PHE PCV13 Risk Groups PGD amended to: • reworded inclusion criteria to be specific to those at risk of pneumococcal disease requiring additional PCV13 • reworded dose section to reflect revised Green Book chapter 25 and clarify when you would provide PCV13 to previously unvaccinated or partially vaccinated individuals	10/05/2017
V03.00	PHE PCV13 Risk Groups PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	14/02/2019
V04.00	PHE PCV13 Risk Groups PGD amended to: • include primary immunisation schedule for those with asplenia, splenic dysfunction, complement disorder or severe immunocompromise under 1 year of age • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	20/12/2019
V05.00	UKHSA PCV13 Risk Groups PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGD and updated references • add a note in criteria for management of clusters and outbreaks of pneumococcal disease • add to cautions section information for premature infants and occurrence of apnoea following vaccination. • include in the off-label the administration of an additional booster as per 'Green Book, Chapter 25' • update the patient advice section in line with the Green Book Chapter 25, 13 January 2020 • add to special considerations information for splenectomy immunisation post bone marrow transplant and timing of vaccination for leukemia	16/02/2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group and the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michael Gregory	Medical Director for Commissioning, NHSEI North West Region
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHS England and Improvement NHSEI (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England & NHS Improvement (South East) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within the NHS England and NHS Improvement South East Region
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England and NHS Improvement (South East) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
South East Regional Medical Director	Dr Vaughan Lewis		**22 Feb 2022**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team.

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSEI and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 7 and Chapter 25 of Immunisation Against Infectious Disease: 'The Green Book'. This PGD does not cover the routine childhood PCV13 immunisation programme which is covered by the UKHSA PCV PGD.
Criteria for inclusion	Individuals who are: • under 2 years who have, or are anticipated to have (see Special considerations / additional information), asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] • from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (such that they did not complete the routine PCV course as part of the national schedule) and who have a medical condition included in Appendix A • over 2 years of age and have, or are anticipated to have (see Special considerations / additional information), severe immunocompromise[2] Note: For the management of clusters and outbreaks of pneumococcal disease see PCV PGD.
Criteria for exclusion[3]	Individuals for whom no valid consent has been received. Individuals who: • are less than 6 weeks of age • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including diphtheria toxoid • have received a dose of PCV13 within the last 4 weeks (Note: national schedule recommends an 8-week interval, see Dose and frequency of administration section) • are aged 10 or above and received a dose of PPV23 within the last 2 years • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken continued over page	The immunogenicity of the vaccine could be reduced in immunosuppressed individuals; however, vaccination is still recommended. Premature infants with asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] should be vaccinated in accordance with 'Green Book' Chapter 25 immunisation schedule and according to their chronological age.

[2] Examples of severe immunocompromise include individuals with bone marrow transplant, acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside this PGDs remit and another form of authorisation will be required

Cautions including any relevant action to be taken (continued)	For premature infants without asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2], the PCV PGD should be used. The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded	If aged less than 6 weeks defer immunisation and provide an appointment as appropriate. If a dose of PCV13 was received within the last 4 weeks defer immunisation for an appropriate interval (see Dose and frequency of administration).In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document the advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13: • Prevenar®13 suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	**Infants <37 weeks gestation** Administration of a two-dose primary series of Prevenar®13 to pre-term infants <37 weeks gestation, with asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2], is contrary to the 3-dose primary schedule detailed in the SPC but is in accordance with the recommendations for individuals with asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] in the 'Green Book', Chapter 7 and Chapter 25.' **Individuals under 2 years** Administration of an additional booster following 2+1 schedule is off-label as the additional booster is not included in the SPC but is in accordance with the recommendations and Chapter 25 of the 'Green Book'. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be administered in accordance with the recommendations in the 'Green Book' Chapter 4 to reduce the risk of bleeding. The vaccine's normal appearance is a uniform white suspension which may sediment during storage. Shake the prefilled syringe well

continued over page

Route / method of administration (continued)	to uniformly distribute the suspension before administering the vaccine. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.
Dose and frequency of administration continued over page	Single 0.5ml dose per administration **Individuals under 1 year of age** Individuals at increased risk of pneumococcal disease due to asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] should receive: • a 2-dose priming schedule of PCV13 vaccine with an 8-week interval* between priming doses administered in the first year of life (commencing no earlier than 6 weeks of age), then • a booster dose to be administered at one year of age (on or after the first birthday), then • a further booster dose, 8 weeks after the first booster. *The immunisation interval may be reduced to 4-weeks if necessary, to ensure the immunisation schedule is completed. All other individuals under 1 year of age should be fully vaccinated in accordance with the routine PCV13 immunisation programme (see the UKHSA PCV PGD and the vaccination of individuals with uncertain or incomplete immunisation status guidance). **Individuals from 1 year to under 2 years of age** Individuals with asplenia, splenic dysfunction (see Appendix A), complement disorder or severe immunocompromise[2], aged between their first and second birthday should receive: • the PCV13 booster routinely scheduled on or shortly after their first birthday followed by • an additional booster dose of PCV13 with an interval of 8 weeks between the PCV13 booster doses. Note: This is the schedule to follow regardless of whether the child had none, one or two routine primary doses of PCV13 in infancy. The intervals may be reduced to one month if necessary, to ensure that the immunisation schedule is completed. **Individuals from 2 years to under 10 years of age** Individuals from 2 years to under 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[2] , who have completed the routine PCV immunisation schedule (with PCV7 or PCV13) do not require further PCV13. Individuals from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (such that they did not complete a PCV course as part of the national schedule) and who have a medical condition included in Appendix A should receive a single dose of PCV13.

Dose and frequency of administration (continued)	Severely immunocompromised[2] individuals, who have not received an additional booster of PCV13 recommended between one and two years of age, should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. **Individuals from 10 years of age** Individuals from 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[2])do not require PCV13. Severely immunocompromised[2] who have not already received an additional booster of PCV13, should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. PCV13 or additional PPV23 are not needed if the individual received PPV23 in the previous 2 years. **Pneumococcal polysaccharide vaccine (PPV23)** Additionally, all individuals with a medical condition included in Appendix A should receive a dose of PPV23 on or after their second birthday (see PPV PGD). Individuals eligible for both PCV13 and PPV23 should have the PCV13 dose first followed by PPV23 at least 2 months later.
Duration of treatment	Single 0.5ml dose
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	PCV13 for additional doses from one year of age for at risk groups is not centrally procured and these should be ordered from the manufacturer/wholesaler. Details are given in the 'Green Book' Chapter 25. Centrally purchased vaccines for the national routine childhood immunisation programme for the NHS can only be ordered via ImmForm, that is vaccines for use for primary immunisation and the booster at one year of age. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Prevenar® 13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar® 13 should be used or discarded. These data are intended to guide health care professionals in case of inadvertent temporary temperature excursions only. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal continued over page	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according

Disposal continued	to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of interactions is available in the SPC, which is available from the electronic Medicines Compendium website.:
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. The most commonly reported adverse reactions include, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting, diarrhoea, arthralgia, myalgia and headache. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website.:
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Vaccination may not result in complete protection in all recipients. Individuals at especially increased risk of serious pneumococcal infection (such as asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. Advise the individual/parent/carer when any subsequent immunisations are due. When administration is postponed advise the individual/parent/carer when to return for vaccination.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Neonates diagnosed at increased risk of pneumococcal disease due to asplenia, splenic dysfunction, complement disorder or severe immunocompromise[2] should be offered immunisation as soon as appropriate (such as with their first primary immunisations) and do not need to wait until the routine offer of PCV13 at 12 weeks of age. Individuals on Eculizumab (Soliris®) therapy are not at increased risk of pneumococcal disease and do not require PPV23 or additional doses of PCV13. Wherever possible, immunisation or boosting of immunosuppressed individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen (see 'Green Book' Chapter 25). Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate. Those requiring splenectomy, where possible, should be vaccinated before elective splenectomy. If it is not practicable to vaccinate before splenectomy, immunisation should be delayed until at least two weeks after the operation (see 'Green Book' Chapter 25). Immunisation of these individuals should not be delayed if this is likely to result in a failure to vaccinate. For the timing of vaccination for leukaemia individuals see 'Green Book' Chapter 25. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 and Chapter 25 of the 'Green Book'). This is not covered by this PGD and should be provided through a Patient Specific Direction (PSD). Splenectomy, chemotherapy or radiotherapy should never be delayed in order to allow time for vaccination.
Records continued over page	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD

Records continued	Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Services must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Pneumococcal conjugate vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 7, January 2020 and Chapter 25, 25 January 2020. https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 • Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. 12 October 2021. http://www.medicines.org.uk/emc/medicine/22689 • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. 26 August 2021. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. • https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

PCV Risk Groups PGD v05.00 Valid from: 01/03/2022 Expiry: 28/02/2024

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

APPENDIX A

Clinical risk groups who should receive the pneumococcal immunisation

(Green Book Chapter 25 Table 25.2)

Clinical risk group	Examples (decision based on clinical judgement)
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Chronic respiratory disease (chronic respiratory disease refers to chronic lower respiratory tract disease)	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below).
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure.
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation. (Re-immunisation with PPV23 is recommended every 5 years)
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis.
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, complement disorder, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO) Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day.
Individuals with cochlear implants	It is important that immunisation does not delay the cochlear implantation.
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery(does not include CSF shunts).